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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/890,442 | 01/31/2002 | Johann Karl | 9793/73 | 3050 |
| 757 | 7590 | 05/04/2004 | EXAMINER | |
| BRINKS HOFER GILSON & LIONE P.O. BOX 10395 CHICAGO, IL 60610 | | | GRUN, JAMES LESLIE | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1641 | |

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 09/890,442 | Applicant(s) KARL ET AL. | |
| | Examiner James L. Grun | Art Unit 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-73 and 75-141 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-73 and 75-141 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1641

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The amendment filed 03 February 2004 is acknowledged and has been entered. Claims 1-19 and 74 have been cancelled. Claim 141 is newly added. Claims 20-73 and 75-141 remain in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

The specification is objected to and claims 20-73 and 75-141 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons of record set forth previously with regard to the similar subject matter of claims 20-73 and 75-140.

Applicant's arguments filed 03 February 2004 have been fully considered but they are not deemed to be persuasive. Applicant's arguments reiterate and reinforce the definition provided on page 6 of the specification which differs from the definition provided on page 10 of the specification and as known to the art. This is not found persuasive for the reasons of record that,

Art Unit: 1641

because of the differing definitions and absent further written description and guidance from applicant, one would not know which sequences or structures were part of the invention.

Claims 134-138 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons of record wherein a deposit requirement was made and applicants were deemed not to be in compliance with the Deposit Rules (37 CFR §§ 1.801-1.809).

Applicant's arguments filed 03 February 2004 have been fully considered but they are not deemed to be persuasive. Applicant urges that page 13 of the specification provides evidence of deposit of the claimed biological materials. This is not found persuasive because the record does not provide evidence that the claimed biological materials are: (1) known and readily available to the public; (2) reproducible from the written description; or, (3) deposited in compliance with the criteria set forth in 37 CFR §§ 1.801-1.809. These specific criteria for a suitable deposit in compliance with the Deposit Rules which would satisfy the enablement requirements of 35 U.S.C. § 112, first paragraph, are set forth in the previous Office action and have not been met by applicant's disclosure for reasons of record.

Claims 29-37, 40, 47-55, 58, 65-73, 77, 84-92, 95, 102-110, 113, 120-128, 136, 140, and 141 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1641

In claims 141, 22, and claims 31, 40, 49, 58, 67, 77, 86, 95, 104, 113, and 122 dependent thereupon, it is not clear what properties are encompassed by “bind simultaneously” because it is not clear if applicant intended a temporal parameter, i.e. a simultaneous sandwich assay in which both antibodies are added at the same time, or a localization limitation, i.e. the antibodies are added sequentially but can remain bound non-competitively at the same time to the polypeptide because of their binding to different epitopes.

Claims 29-37 duplicate the subject matter as claimed in claims 20-28 and provide no further limitation thereof.

Claims 47-55 duplicate the subject matter as claimed in claims 38-46.

Claims 65-73 duplicate the subject matter as claimed in claims 56-64.

Claims 84-92 duplicate the subject matter as claimed in claims 75-83.

Claims 102-110 duplicate the subject matter as claimed in claims 93-101.

Claims 120-128 duplicate the subject matter as claimed in claims 111-119.

Claim 136 is vague and indefinite in the recitation of “the antibody...is equivalent” because it is not clear what applicant intends as encompassed or excluded. Without a clear and unambiguous description and recitation of “equivalent” and how one performs a comparison therefor, the metes and bounds of the invention as claimed cannot be determined.

In claim 140, the interrelationships of the steps and components of the method are not clear, e.g. the connection between selecting clones and producing antibodies is not clear.

Art Unit: 1641

Applicant's arguments filed 03 February 2004 have been fully considered but they are not deemed to be persuasive. Applicant urges that a temporal parameter such that the antibodies bind at the same time is intended by the recitation of "bind simultaneously." This is not found persuasive for the reasons set forth above. Applicant urges that recitation of "equivalent" is clear. This is not found persuasive for the reasons of record. Notwithstanding applicant's arguments to the contrary, applicant's amendments have not clarified claim 140 for the reasons set forth above.

Claims 130-131 remain rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. There is no indication that the product(s) as claimed are isolated and no claimed degree of purity for the product(s) which would indicate "the hand of man". Thus, the products as claimed are considered a product of nature which is non-statutory subject matter.

Applicant's arguments filed 03 February 2004 have been fully considered but they are not deemed to be persuasive. Applicant urges that the specification teaches that the antibodies are isolated and purified. This is not found persuasive because, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

Claims 129-133, 136, and 139 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Hall (U.S. Pat. No. 5,786,163) for reasons of record. As set forth, the reference

Art Unit: 1641

teaches the use of the full length N-terminal fragment, BNP(1-76), made by using techniques well known in the art (e.g. col. 3, lines 61-67), and there is nothing on the record which serves to distinguish a recombinantly made BNP(1-76) peptide from the peptide made or isolated by an alternative means. As set forth, the reference clearly teaches sandwich assays for the determination of BNP(1-76) in samples of body fluids, in particular from patients suffering from heart disease.

Claims 20-73, 129-133, 136, and 139-141 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hall (U.S. Pat. No. 5,786,163) in view of Hunt et al. (Clin. Endocrinol. 47: 287, 1997) for reasons of record in the prior rejection of the similar subject matter of claims 20-73, 129-133, 136, and 139.

Claims 20-73, 75-133, 136, and 139-141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hall (U.S. Pat. No. 5,786,163) in view of Hunt et al. (Clin. Endocrinol. 47: 287, 1997) as applied to claims 20-73, 129-133, 136, and 139-141, and further in view of Seilhamer et al. (WO 89/12069) and Sudoh et al. (Biochem. Biophys. Res. Comm. 159: 1427, 1989) for reasons of record in the prior rejection of the similar subject matter of claims 20-73, 75-133, 136, and 139.

Applicant's arguments filed 03 February 2004 have been fully considered but they are not deemed to be persuasive. Applicant urges that the references of Hall and/or Hunt et al. only exemplify antibodies elicited to peptides derived from BNP(1-76) and their use in competitive immunoassays. This is not found persuasive for the reasons of record. Notwithstanding

Art Unit: 1641

applicant's arguments to the contrary, the disclosure of the references, particularly that of Hall, are considered as a whole and are not limited only to that which is specifically exemplified. Applicant urges that the prior art does not teach a sandwich assay of the detection limit as instantly claimed. This is not found persuasive for the reasons of record that one would have been motivated to optimize the assay to detect antigen in the concentration range known for the antigen in biological fluid samples. Applicant urges that Seilhamer et al. or Sudoh et al. do not provide guidance to NT-proBNP (BNP(1-76)). In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, as set forth, Hall desires the use of full length BNP(1-76) for immunization and immunoassay methods and Seilhamer et al. teach that any encoded subsegment of human preproBNP and proBNP, in view of Sudoh et al., can be produced in a variety of ways, including using recombinant methods.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1641

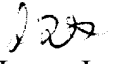
A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

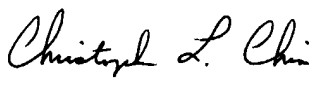
Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone numbers for official facsimile transmitted communications to TC 1600, Group 1640, are (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.


James L. Grun, Ph.D.
April 29, 2004


CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641